

these priority populations are encouraged.

Sharon B. Arnold,
Deputy Director.

[FR Doc. 2017-13396 Filed 6-26-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meeting of the National Advisory Council for Healthcare Research and Quality

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality.

DATES: The meeting will be held on Wednesday, July 26, 2017, from 8:30 a.m. to 2:45 p.m.

ADDRESSES: The meeting will be held at AHRQ, 5600 Fishers Lane, Rockville, Maryland, 20857.

FOR FURTHER INFORMATION CONTACT: Jaime Zimmerman, Designated Management Official, at the Agency for Healthcare Research and Quality, 5600 Fishers Lane, Mail Stop 06E37A, Rockville, Maryland 20857, (301) 427-1456. For press-related information, please contact Alison Hunt at (301) 427-1244 or Alison.Hunt@ahrq.hhs.gov.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact the Food and Drug Administration (FDA) Office of Equal Employment Opportunity and Diversity Management on (301) 827-4840, no later than Wednesday, July 19, 2017. The agenda, roster, and minutes will be available from Ms. Bonnie Campbell, Committee Management Officer, Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, Maryland 20857. Ms. Campbell's phone number is (301) 427-1554.

SUPPLEMENTARY INFORMATION:

I. Purpose

The National Advisory Council for Healthcare Research and Quality is authorized by Section 941 of the Public Health Service Act, 42 U.S.C. 299c. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director of AHRQ on

matters related to AHRQ's conduct of its mission including providing guidance on (A) priorities for health care research, (B) the field of health care research including training needs and information dissemination on health care quality and (C) the role of the Agency in light of private sector activity and opportunities for public private partnerships. The Council is composed of members of the public, appointed by the Secretary, and Federal ex-officio members specified in the authorizing legislation.

II. Agenda

On Wednesday, July 26, 2017, there will be a subcommittee meeting for the National Healthcare Quality and Disparities Report scheduled to begin at 7:30 a.m. This meeting is open to the public. The Council meeting will convene at 8:30 a.m., with the call to order by the Council Chair and approval of previous Council summary notes. The meeting is open to the public and will be available via webcast at www.webconferences.com/ahrq. The meeting will begin with an update on AHRQ's current research, programs, and initiatives. The agenda will also include an update on AHRQ's work in learning health care systems and AHRQ's EvidenceNOW initiative, and will focus on the use of AHRQ data and analytics to answer emerging policy questions. The final agenda will be available on the AHRQ Web site at www.AHRQ.gov no later than Wednesday, July 19, 2017.

Sharon B. Arnold,
Deputy Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Drug Therapy for Early Rheumatoid Arthritis in Adults—An Update

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of *Drug Therapy for Early Rheumatoid Arthritis in Adults—An Update*, which is currently being conducted by the

AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: Submission Deadline on or before July 27, 2017.

ADDRESSES: Email submissions: SEADS@epc-src.org.

Print submissions:

Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, P.O. Box 69539, Portland, OR 97239.

Shipping Address (FedEx, UPS, etc.): Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, 3710 SW U.S. Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239.

FOR FURTHER INFORMATION CONTACT: Ryan McKenna, Telephone: 503-220-8262 ext. 51723 or Email: SEADS@epc-src.org.

SUPPLEMENTARY INFORMATION: AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a). The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Drug Therapy for Early Rheumatoid Arthritis in Adults—An Update*.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Drug Therapy for Early Rheumatoid Arthritis in Adults—An Update*, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: <https://effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=2475>.

This is to notify the public that the EPC Program would find the following information on *Drug Therapy for Early Rheumatoid Arthritis in Adults—An Update* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.
- For completed studies that do not have results on ClinicalTrials.gov,

please provide a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.

■ *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

■ Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program Web site and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: <https://www.effectivehealthcare.ahrq.gov/index.cfm/join-the-email-list1/>.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

The Key Questions

Key Question (KQ) 1

For patients with early Rheumatoid Arthritis (RA), do drug therapies differ in their ability to reduce disease activity, slow or limit the progression of radiographic joint damage, or induce remission?

KQ 2

For patients with early RA, do drug therapies differ in their ability to improve patient-reported symptoms, functional capacity, or quality of life?

KQ 3

For patients with early RA, do drug therapies differ in harms, tolerability, patient adherence, or adverse effects?

KQ 4

What are the comparative benefits and harms of drug therapies for early RA in subgroups of patients based on disease activity, prior therapy, demographics (e.g., women in their childbearing years), concomitant therapies, and presence of other serious conditions?

Contextual Questions (CQs)

Contextual questions are not systematically reviewed and use a "best evidence" approach. Information about the contextual questions may be included as part of the introduction or discussion section and related as appropriate to the Systematic Review.

CQ 1

Does treatment of early RA improve disease trajectory and disease outcomes compared with the trajectory or outcomes of treatment of established RA?

CQ 2

What barriers prevent individuals with early RA from obtaining access to indicated drug therapies?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

Populations

Inclusion

- I. *All KQs:* Adult outpatients ages 19 or older with an early RA diagnosis, defined as 1 year or less from disease diagnosis; we will include studies with mixed populations if >50% of study populations had an early RA diagnosis
- II. *KQ 4 only:* Subpopulations by age, sex/gender, race/ethnicity, disease activity, prior therapies, concomitant therapies, and other serious conditions

Exclusion

Adolescents and adult patients with disease greater than 1 year from diagnosis.

Intervention/Exposure

Inclusion

- I. FDA approved
 - A. *Corticosteroids:* Methylprednisolone, prednisone, prednisolone
 - B. *csDMARDs:* Hydroxychloroquine, leflunomide, methotrexate, sulfasalazine

- C. *TNF biologics:* Adalimumab, certolizumab pegol, etanercept, golimumab, infliximab
- D. *Non-TNF biologics:* Abatacept, rituximab, tocilizumab
- E. *tsDMARDs:* Tofacitinib
- F. *Biosimilars:* Adalimumab-atto, infliximab-dyyb, infliximab-abda, etanercept-szzs

II. Under review by FDA

- A. *Non-TNF biologics:* Sarilumab, sirukumab

Exclusion

Anakinra is excluded because, although it is approved for RA, clinically it is not used anymore for this population.

Comparator

Inclusion

- I. For head-to-head RCTs, head-to-head nRCTs, and prospective, controlled cohort studies (all KQs): Any active intervention listed above
- II. For additional observational studies of harms (i.e., overall [KQ 3] and among subgroups [KQ 4]: Any active intervention listed above or no comparator (e.g., postmarketing surveillance study of an active intervention with no comparison group)
- III. For double-blinded, placebo-controlled trials for network meta-analysis (all KQs): Placebo

Exclusion

All other comparisons, including active interventions not listed above.

Outcomes

Inclusion

- I. *KQs 1, 4:* Disease activity, radiographic joint damage, remission
- II. *KQs 2, 4:* Functional capacity, quality of life, patient-reported symptoms
- III. *KQs 3, 4:* Overall risk of harms, overall discontinuation, discontinuation because of adverse effects, risk of serious adverse effects, specific adverse effects, patient adherence

Exclusion

All other outcomes not listed.

Timing

Inclusion

All KQs: At least 3 months of treatment.

Exclusion

<3 months treatment.

Settings**Inclusion**

All KQs: Outpatients.

Exclusion

Inpatients.

Country Setting**Inclusion**

All KQs: Any geographic area.

Exclusion

None.

Study Designs**Inclusion**

- I. For all KQs (*i.e.*, benefits and harms overall [KQs 1, 2, 3] and among subgroups [KQ 4]), we will include head-to-head RCTs and nRCTs; prospective, controlled cohort studies ($N \geq 100$); double-blinded, placebo-controlled trials for network meta-analysis; and SRs for identification of additional references only.
- II. For studies of harms (*i.e.*, overall [KQ 3] and among subgroups [KQ 4]), we will also include any other observational study (*e.g.*, cohort, case-control, large case series, post marketing surveillance) ($N \geq 100$).

Exclusion

All other designs not listed.

Publication Language**Inclusion**

All KQs: English.

Exclusion

Languages other than English.

Sharon B. Arnold,

Deputy Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Psychological and Pharmacological Treatments for Adults With Posttraumatic Stress Disorder (PTSD): A Systematic Review Update

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking

scientific information submissions from the public. Scientific information is being solicited to inform our review of *Psychological and Pharmacological Treatments for Adults with Posttraumatic Stress Disorder (PTSD): A Systematic Review Update*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before July 27, 2017.

ADDRESSES:

Email submissions: SEADS@epc-src.org.

Print submissions:

Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, P.O. Box 69539, Portland, OR 97239.

Shipping Address (FedEx, UPS, etc.): Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, 3710 SW U.S. Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239.

FOR FURTHER INFORMATION CONTACT:

Ryan McKenna, Telephone: 503-220-8262 ext. 51723 or Email: SEADS@epc-src.org.

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Psychological and Pharmacological Treatments for Adults with Posttraumatic Stress Disorder (PTSD): A Systematic Review Update*. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.*, details of studies conducted). We are looking for studies that report on *Psychological and Pharmacological Treatments for Adults with Posttraumatic Stress Disorder (PTSD): A Systematic Review Update*, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: <https://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?>

[pageaction=displayproduct&productid=2478](https://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=2478).

This is to notify the public that the EPC Program would find helpful the following information on *Psychological and Pharmacological Treatments for Adults with Posttraumatic Stress Disorder (PTSD): A Systematic Review Update*:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*

- *For completed studies that do not have results on ClinicalTrials.gov*, please provide a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.

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Your contribution will be very beneficial to the EPC Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

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